

more, regulatory requirements stipulate that a new orphan status application must be submitted for each indication. Under EMA regulations, orphan and non-orphan indications cannot be granted under the same marketing authorization. Although expansions between orphan and non-orphan indications are more common in the US, no examples of expansion from a non-orphan to orphan indication were identified by the authors. **CONCLUSIONS:** While indication expansion between orphan indications is relatively common, examples of expansion into or out of orphan indications are less frequent due to the regulatory restrictions. Pricing and reimbursement dynamics in all cases are reflective of the trade-offs between price potential and population size across indications.

PHP15

PRICE NEGOTIATIONS IN KOREAN PHARMACEUTICAL BENEFIT SYSTEM: HOW COMPATIBLE WITH CEA?

Kwon H

National Health Insurance Corporation, Seoul, Seoul, South Korea

OBJECTIVES: Korea introduced a new positive list system in 2007 together with a price negotiation procedure. Importantly, these two systems are run by two different, independent organizations, namely the Health Insurance Review & Assessment Service (HIRA) and the National Health Insurance Corporation (NHIC). HIRA reviews the cost-effectiveness data in submissions and makes listing decisions, then NHIC takes over and sets the reimbursement price via negotiations with manufacturers. The aim of this study is to compare the difference in price after cost-effectiveness appraisal by HIRA and price negotiation by NHIC, and to analyze the factors that NHIC has considered to determine the reimbursement price.

METHODS: All 35 submissions made to the NHIC between August 2007 and June 2008 were reviewed. 19 submissions concluded with agreement, 15 failed and one case was suspended. In this review only 15 cases of successful negotiations were included. The level of the reimbursement price compared to the submitted price for both essential drugs and non-essential ones and factors affecting the final price were analyzed. **RESULTS:** The discrepancy between reimbursement price and cost-effective price was about $12.33 \pm 11.44\%$ on average. For 3 essential drugs, the price level was almost equal to the submitted price whereas the average level was $84.94 \pm 11.21\%$ of the cost-effective price for non-essential drugs. The major factors affecting negotiations to determine the final price were narrowed down to total cost of substitutes, the foreign price, and the pharmaceutical budget impact. **CONCLUSIONS:** Our findings have demonstrated that drug pricing within the new environment has been done independently of cost-effectiveness appraisal. The payer has exhibited limited bargaining power for essential drugs. Overall, 87.67% of the cost-effective price was accepted during price negotiations, and the total cost of substitutes, foreign prices and pharmaceutical budget impact were considered equally when fixing the reimbursement price. A limitation of this study is that the result may not be generalized because of insufficient cases.

PHP16

EXTRAPOLATING STRATEGIC INSIGHTS THROUGH MARKET SEGMENTATION: A CONCEPTUAL FRAMEWORK

Forster L, Wild L

Double Helix Consulting, London, UK

OBJECTIVES: Primary research is often only conducted in a limited number of key markets despite a product being launched across a wider range of countries. In order to understand the implications of research findings across geographies, markets can be grouped by common underlying factors. **METHODS:** Market segmentation frameworks were developed based on key decision drivers which can be applied at different points in a product lifecycle. Within each framework, markets can be segmented in up to two domains to distinguish segments. In-depth secondary research was conducted in EU27 markets to understand key pricing, reimbursement, access and uptake processes. Qualitative analysis of these findings permitted us to place markets in the segmentation framework, allowing extrapolation of findings across similar markets. **RESULTS:** Markets can be segmented in several domains, depending on areas of interest for the research in question. For example, in the case of peri-launch segmentation, most new pharmaceuticals aim to secure optimal pricing and reimbursement – therefore an understanding of similarities and differences in these areas are of greatest interest. Markets can be assessed in terms of HTA data requirement, degree of centralization of decision making, pricing regulations (fixed vs. 'free' pricing) or pricing decision drivers. This approach was applied to understanding market similarities for a novel, hospital administered product in a rare disease area. All 27 EU markets were segmented by level of price regulation into three groups: price set by manufacturer, price set through negotiation or strict price regulation. Understanding pricing drivers in each group allowed results from primary research undertaken in only 6 of these markets to be used by the manufacturer in all EU27 markets. **CONCLUSIONS:** Applying these conceptual frameworks to drive market segmentation, key similarities and differences between markets can be used to extrapolate findings from primary market research, or determine what strategic options are applicable to a given market.

PHP17

CHARACTERISTICS OF HIGH COST AMBULATORY DRUGS IN FRENCH HEALTH CARE SYSTEM

Gridchyna J, Aulois-Griot M, Pulon C, Maurain C, Bégaud B

Université Bordeaux Segalen, Bordeaux, France

OBJECTIVES: In 1994, in French health care system, a supplement status for ambulatory reimbursement drugs, called "exception drugs", was established. This status enables to reimburse only specified indications of particularly costly drugs. In this study we analyze what characteristics a drug should possess in order to be considered as an "exception drug". **METHODS:** Included in the study, were drugs

that had status of "exception drugs" as of April 2011. The clinical (actual benefit, improvement of actual benefit) and economic (amount reimbursed by National Health Insurance) characteristics were collected from official and publicly available websources, as well as supplement restrictions for prescription (any prescription or only the first one must be accomplished by a hospital practitioner; prescription must be accomplished by a specialist; or prescription requires specific following during the treatment). **RESULTS:** As of April 2011, there were 56 "exception drugs" in trade name and 30 in generic name. The drugs from 9 ATC classes level I were presented; the most numerous were A16 (Other alimentary tract and metabolism), H01 (Pituitary and hypothalamic hormones and analogues), B03 (Antianemic preparations). Supplement restrictions for prescription was applied to 33 drugs. Some "exception drugs" (10) had also the status of drugs financed out of DRG payment system. Most of the drugs, 91.07% (51/56) had high level of actual benefit. Around half of the "exception drugs", 42.86% (24/56) had level of improvement in actual benefit from I to III. In 2009, part of reimbursed amount of "exception drugs" was 7.73% from all reimbursed drugs, whereas in 2004 it was 2.85%. Interestingly, in 2009 four "exception drugs" constituted about 1% of the reimbursed amount each, and 40 – less than 0.1%. **CONCLUSIONS:** The analyzed types of characteristics, both economic and clinical, can be used as criteria for establishing the status of "exception drug".

PHP19

DOES PHARMACEUTICAL PRICE REGULATION AFFECT THE ADOPTION OF GENERIC COMPETITION IN THE OECD?

Varol N¹, Costa-i-Font J², McGuire AJ³

¹United Biosource Corporation, London, UK, ²London School of Economics and Political Science, London, UK, ³LSE Health and Social Care, London, UK

OBJECTIVES: Generic competition is an effective cost-containment mechanism that improves static efficiency and stimulates pharmaceutical innovation. No prior study has empirically analysed the relative delays in adoption of generic competition within the OECD. This study aims to investigate how price regulations in the OECD affect timing of generic adoption following the first global generic launch.

METHODS: Drawing upon data from 1999 to 2008, we estimate the impact of ex-ante price and market size expectations on the probability of generic launch using discrete-time duration modeling with cloglog and logit regressions. The econometric strategy employs both parametric and non-parametric duration dependence and includes controls for local generic competition, firm characteristics and molecule heterogeneity. **RESULTS:** Ex-ante profit expectations result in faster adoption; both expected price and market size increase the probability of launch. Our findings suggest that neither molecule nor firm characteristics have a significant effect on generic adoption across different specifications. **CONCLUSIONS:** Evidence indicates that regulation has a significant impact on timing of adoption; however, generic competitors tend to follow a locally oriented strategy in contrast to research-intensive pharmaceutical firms.

PHP20

MARKET ACCESS BARRIERS FOR BIOSIMILARS IN SPAIN AND GERMANY: EPOETIN ALFA EXAMPLE

Hurtado P, Vieta A, Espinós B, Badia X

IMS Health, Barcelona, Barcelona, Spain

OBJECTIVES: Biosimilars are predicted to reduce prices of biologicals. Among biosimilars, epoetin alfa has the largest market penetration in Germany and Spain. The aim of this study was to describe the political, technological, economical and social factors that impact on epoetin alfa sales and price in both European countries, which greatly differ in their generic market size. **METHODS:** Revisions of regulatory legislation and policies regarding biosimilars at country and European levels have been conducted. Estimations of market shares in units for epoetin alfa originator and biosimilars plus darbopoetin alfa, a second generation biological, were calculated. Epoetin alfa pricing trend was followed. All data was extracted from IMS MIDAS database, using standard units and ex-manufacturer price.

RESULTS: Both countries are under the same regulatory framework and have policies that promote generic penetration, although automatic biosimilar substitution is banned. Price of first launched biosimilar was approximately 30% below originator price in both countries. In Germany, originator price decreased about 16% after launch of second biosimilar, whereas in Spain, originator price trend have no changes to date. Regarding originator market shares, they did not change after launch of biosimilars in Spain, while in Germany marked reductions were observed along with biosimilars market share increases. In Spain, market shares of darbopoetin alfa were reduced when epoetin alfa biosimilar sales started, but no changes of the kind were documented in Germany. **CONCLUSIONS:** Although both countries face similar political and technological factors; in Spain, social and economical ones could negatively impact stakeholder perception. In this country, the introduction of biosimilars do not modify market share of the originator despite it has a price about 30% higher. In Germany, stakeholders pose minimum resistance to biosimilars, as market share and price of originator are immediately reduced after the entry of biosimilars.

PHP21

ADOPTION OF NEW MEDICINES IN THE OECD: REGULATION, INNOVATION AND SCALE

Varol N¹, Costa-i-Font J², McGuire AJ³

¹United Biosource Corporation, London, UK, ²London School of Economics and Political Science, London, UK, ³LSE Health and Social Care, London, UK

OBJECTIVES: Most OECD countries employ pricing controls to contain rising health care expenditures. The recent financial crisis has resulted in further pressure to